

WE CLAIM:

- 5 1. A substantially pure antibody or antibody fragment specific for the initial peptide sequence for whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the reactive portion with the antibody.
2. The antibody of Claim 1 wherein the antibody is a monoclonal antibody.
- 10 3. The antibody of Claim 1 wherein the antibody is a polyclonal antibody.
- 15 4. A method for measuring the amount of whole parathyroid hormone in a sample comprising:
- 20 a) adding to the sample a labeled antibody or antibody fragment specific for the initial peptide sequence for whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present;
- b) allowing the labeled antibody to bind to any whole parathyroid hormone present, thereby forming a complex, and
- c) measuring the amount of labeled complex.
- 25 5. The method of Claim 4 wherein the labeled parathyroid hormone antibody or antibody fragment is a monoclonal antibody.
6. The method of Claim 4 wherein the labeled parathyroid hormone antibody or antibody fragment is a polyclonal antibody.

Sub B2 7. The method of Claim 4 wherein a second antibody is added which is bound to a solid support and specifically binds to a portion of wPTH other than the initial peptide sequence which binds to the first antibody.

5 8. The method of Claim 7 wherein the solid support is selected from the group consisting of a protein binding surface, colloidal metal particles, iron oxide particles, latex particles, and polymeric beads.

9. The method of Claim 8 wherein the complex precipitates from solution.

Sub B2 10 10. The method of Claim 4 wherein the label or signal generating component is selected from the group consisting of chemiluminescent agents, colorimetric agents, energy transfer agents, enzymes, fluorescent agents, and radioisotopes.

15 11. The method of Claim 7 also comprising a third antibody specific for the C-terminal portion of parathyroid hormone C-terminal fragment, but which is not reactive to the initial peptide sequence, is added to the sample thereby reduce binding reaction interference from any parathyroid C-terminal fragments present in the sample.

20 12. A method for measuring the amount of whole parathyroid hormone in a sample comprising:

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- a) adding to the sample a first antibody or antibody fragment specific for the initial peptide sequence for whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present;
 - b) allowing the first antibody to bind to any whole parathyroid hormone present, thereby forming a complex;

- See B3
- c) labeling the complex by means of adding a second antibody that has a label or signal generating component attached thereto and that specifically binds to a portion of whole PTH other than the initial peptide sequence which binds to the first antibody; and
- 5 d) measuring the amount of labeled complex.

13. The method of Claim 12 wherein the second labeled antibody is added sequentially or simultaneously with the first whole parathyroid hormone antibody.

- 10 14. The method of Claim 12 wherein the first whole parathyroid hormone antibody is bound to a solid support.

- See B3
- 15 15. The method of Claim 12 wherein the second labeled antibody binds either to the mid-portion of whole PTH or the C-terminal of whole PTH and also comprising adding at least a third antibody which specifically binds to an epitope left open after whole PTH binds to the first antibody and the second antibody, thereby forming a precipitating mass.

16. The method of Claim 15 wherein the C-terminal antibody is bound to a solid support.

- 20 17. A method for measuring whole parathyroid hormone by means of a precipitating or turbidometric immunoassay comprising:

- 25 a) adding to a sample an antibody or antibody fragment specific for the initial peptide sequence for whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all whole parathyroid hormone present, said antibody being attached to a colloidal particle or moiety which can be used to detect a signal change;
- 30 b) allowing the antibody to bind to any whole parathyroid hormone present, thereby forming a complex; and

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c) measuring the change in signal due to the formation of the complex.

5 18. A kit containing reagents for performing an assay for whole parathyroid hormone comprising:

- 10 a) a substantially pure antibody or antibody fragment specific for the initial sequence of whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide; and
- b) a labeling component that binds to whole parathyroid hormone, but not to the parathyroid hormone peptide sequence VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1).

15 19. The kit of Claim 18 also comprising an antibody specific for the C-terminal portion of parathyroid hormone C-terminal fragment.

20 20. A kit containing reagents for performing an assay for whole parathyroid hormone comprising:

- a) a substantially pure antibody or antibody fragment specific for the initial sequence of whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1) wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide having a signal generating component attached thereto; and
- 25 b) a second antibody that binds to whole parathyroid hormone, but not to the parathyroid hormone peptide sequence VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1) which is bound to a solid support.

21 The kit of Claim 20 also comprising an antibody specific for the C-terminal portion of parathyroid hormone.

22. A method for measuring the amount of functional N-terminal parathyroid hormone fragment and whole parathyroid hormone in a sample comprising:

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- a) adding to the sample a first antibody or antibody fragment specific for the initial peptide sequence for whole parathyroid hormone which comprises a domain for adenylate cyclase activation, VAL-SER-GLU-ILE-GLN-LEU-MET (SEQ ID No. 1), wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all functional N-terminal parathyroid hormone fragment and whole parathyroid hormone present;
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- b) adding to the sample a second antibody or antibody fragment specific for the peptide sequence of amino acids 28 to 34, (SEQ ID NO. 2), which comprises a domain for protein kinase C activation, wherein at least four amino acids in this sequence are part of the antibody reactive portion of the peptide, in an amount sufficient to bind all functional N-terminal parathyroid hormone fragment and whole parathyroid hormone present, at least the first antibody or the second antibody is labeled;
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- c) allowing the first antibody and second antibody to bind to any N-terminal parathyroid hormone fragment or whole parathyroid hormone present, thereby forming a complex; and
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- d) measuring the amount of labeled complex.

23. A method for differentiating between a person having substantially normal parathyroid hormone function and having hyperparathyroidism comprising measuring whole parathyroid hormone levels in the person.

25 24. A method for differentiating between a chronic uremia patient having substantially normal active parathyroid hormone levels and having hyperparathyroidism comprising measuring whole parathyroid hormone levels in the person.